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Stelios Tzannis

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EXAMINER

KIM, YUNSOO

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STELIOS TZANNIS,
ROBERT A. PLATZ, and BHAS A. DANI

Appeal 2009-008102
Application 10/714,575
Technology Center 1600

Decided: April 12, 2010

Before JAMES T. MOORE, *Vice Chief Administrative Patent Judge*,
LORA M. GREEN, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a reconstituted antibody composition. The Patent Examiner rejected the claims for lack of novelty. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification states that the invention relates to “antibody-containing particles that can form powdered compositions,” “methods for preparing reconstituted compositions,” and “methods for administering the reconstituted compositions to patients.” (Spec. 1:[0002].) According to the Specification, lyophilized (aka freeze dried) antibody formulations “are known to have relatively long reconstitution times.” (*Id.* at 4:[0012].) “The present invention is therefore directed to provide, among other things, antibody-containing formulations that have relatively quick reconstitution times so as to solve problems associated with administering antibodies.” (*Id.*)

Claims 31-56 and 59 are on appeal.¹ Claim 31 is representative and reads as follows:

31. A reconstituted composition comprising an antibody in an amount of from about 25 mg/mL to about 200 mg/mL, a diluent and an optional pharmaceutically acceptable excipient, wherein the reconstituted composition is
- (i) formed from adding the diluent to a spray-dried powder comprised of the antibody and the optional excipient, and
 - (ii) is a visually clear reconstituted composition within about 10 minutes of being formed.

The Examiner rejected claims 31-56 and 59 under 35 U.S.C. § 102(b) as anticipated by Andya.² Claims 32-56 and 59 have not been argued separately and therefore stand or fall with claim 31. 37 C.F.R. § 41.37(c)(1)(vii).

¹ The Examiner withdrew claims 1-30 and 61-74 from consideration, and Appellants cancelled claims 57 and 58. (App. Br. 5.)

² US 6,267,958 B1, issued to James Andya et al., Jul. 31, 2001.

ANTICIPATION

The Issue

The Examiner's position is that Andya described a reconstituted composition comprising about 50 mg/mL antibody, diluent, buffer and sucrose as an excipient. (Ans. 3.) The Examiner found that Appellants' claim elements (i) reconstitution from a spray-dried powder, and (ii) visual clarity within about 10 minutes, did not distinguish Andya's composition reconstituted from a lyophilized powder. Specifically, the Examiner found that (i) "the patentability of the product does not depend on its method of production," and (ii) "being a 'visually clear reconstituted composition within about 10min' is an inherent property" of Andya's composition. (*Id.* at 4.)

Appellants contend that:

In view of the different reconstitution times associated with the lyophilized formulations shown in the specification at paragraph [0162] (which are also of the type disclosed in Andya et al.) and the spray dried formulations encompassed by the claims, it simply cannot be said that a visually clear reconstituted composition within about 10 minutes of being formed is "an inherent property of antibody formulations" generally.

(App. Br. 17.) According to Appellants, they have demonstrated that reconstituted lyophilized compositions, such as Andya's, "will not inherently become a visually clear reconstituted composition within about 10 minutes of being formed." (*Id.*) Appellants further argue that Andya "fails to disclose the feature of a spray-dried powder" recited in the claims. (*Id.*)

The issues with respect to this rejection are:

Whether the evidence of record accounts for the “spray-dried powder” limitation;

have Appellants rebutted the Examiner’s finding that Andya’s composition inherently became visually clear within about 10 minutes; and

have Appellants established that a reconstitution time “within about 10 minutes” means the claimed reconstituted composition is necessarily different from Andya’s reconstituted composition?

Findings of Fact

1. According to the Specification, “[p]articles prepared from comminuting freeze-dried materials are [] different from particles prepared from spray-drying techniques.” (Spec. 19-20:[0092].)
2. “Reconstitution Time Analysis” means: “[d]uring the reconstitution process, the time required to reach complete reconstitution, evidenced by achievement of visual clarity, was determined and reported as reconstitution time.” (*Id.* at 35:[0151].)
3. We find the Specification’s explanation at 35:[0151] characterizes “reconstituted” as meaning visually clear.
4. The Specification describes an “Example 1.” (*Id.* at 36-38.)
5. Example 1 reports the reconstitution times for a spray dried formulation and a lyophilized formulation were <5 minutes and 11 minutes, respectively. (*Id.* at 37-38:[0162], Table II).

Principles of Law

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Anticipation is an issue of fact, and the question whether a claim limitation is inherent in a prior art reference is a factual issue.

In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted).

“If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).

Where . . . the claimed and prior art products . . . are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . .

In re Best, 562 F.2d 1252, 1255 (CCPA 1977).

Analysis

It is undisputed that Andya described a reconstituted liquid composition comprising the claimed amount of antibody, a diluent, and an optional excipient. *Compare* Ans. 3 *with* App. Br. 16. It is also undisputed that Andya’s liquid composition was reconstituted from a lyophilized powder, not from a spray-dried powder as claimed.

The Examiner found that the reconstituted liquids in the prior art and those currently claimed were the same, although the powders used in the reconstitution process were made in different ways. The Examiner’s evidence is that both liquids contained the same ingredients and were visually clear. Given that evidence, we find that the Examiner properly

shifted the burden to Appellants to prove that Andya's reconstituted liquid did not inherently possess the characteristics of the claimed liquid. *See Thorpe*, 777 F.2d at 697; *see also Best*, 562 F.2d at 1255.

For evidence of a difference between their reconstituted composition and Andya's reconstituted composition, Appellants rely on Specification paragraph [0162]. (App. Br. 13.) Paragraph [0162] compares the reconstitution time for spray-dried and lyophilized formulations, with reconstitution time meaning the time needed to reach visual clarity. (FF2; FF3.) As shown, a spray-dried formulation reached visual clarity in <5 minutes, and a lyophilized formulation reached visual clarity in 11 minutes. (FF5.) The Examiner was not persuaded that the difference in time needed for the solid to become a visually clear liquid means there is a difference between the visually clear liquids. Put another way, although it took the lyophilized formulation 11 minutes to reach visual clarity, and the spray-dried formulation reached visual clarity in <5 minutes, the Examiner found no difference between the visually clear liquids. Further, the Examiner found that the claim recitation "within about 10 minutes," read on the 11 minute reconstitution time that Appellants attribute to Andya's type reconstitutions. Appellants offer no evidence that the visually clear liquids are different. We find that Appellants have not rebutted the Examiner's evidence that Andya's reconstituted composition is the same as the reconstituted composition now claimed.

CONCLUSIONS OF LAW

Appellants have not shown the evidence of record does not account for the "spray-dried powder" limitation;

Appellants have not rebutted the Examiner's finding that Andya's composition inherently became visually clear within about 10 minutes; and

Appellants have not established that a reconstitution time "within about 10 minutes" means the claimed reconstituted composition is necessarily different from Andya's reconstituted composition.

SUMMARY

We affirm the rejection of claims 31-56 and 59 under 35 U.S.C. § 102(b) as anticipated by Andya.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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